201-14658

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August 11, 2003

By Mail
Marianne L. Horinko, Acting Administrator
U.S. EPA
PO Box 1473
Merrifield, VA 22116

Attn: Chemical Right-to-Know Program – Test Plan Submission from HERTG
Registration Number

Dear Administrator Horinko:

The American Chemistry Council Petroleum Additives Panel (Panel) Health, Environmental, and Regulatory Task Group (HERTG) submits for review and public comments its test plan as well as related robust summaries for Thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide (CAS #18760-44-6) under the Environmental Protection Agency's High Production Volume (HPV) Chemical Challenge Program. The HERTG understands that there will be a 120-day review period for the test plan report and that all comments generated by or provided to EPA will be forwarded to the HERTG for consideration.

Thank you in advance for your attention to this matter. If you have any questions regarding the test plan report or the robust summaries, please contact Sarah Loftus McLallen at 703-741-5614 (telephone), 703-741-6091 (telefax) or Sarah_McLallen@americanchemistry.com (e-mail).

Sincerely yours,

cc: HERTG Members

HIGH PRODUCTION VOLUME (HPV)

CHALLENGE PROGRAM

TEST PLAN

For

Thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide

Prepared by
The American Chemistry Council
Petroleum Additives Panel
Health, Environmental, and Regulatory Task Group

August 8, 2003

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LIST OF MEMBER COMPANIES IN THE
HEALTH, ENVIRONMENTAL AND REGULATORY TASK GROUP

The Health, Environmental, and Regulatory Task Group (HERTG) of the American Chemistry Council Petroleum Additives Panel includes the following member companies:

BP plc

Chevron Oronite Company, LLC

Crompton Corporation

Ethyl Corporation

ExxonMobil Chemical Company

Ferro Corporation

Infineum

The Lubrizol Corporation

Rhein Chemie Corporation

Rhodia, Inc. (formerly Albright & Wilson Americas Inc.)

1.0 INTRODUCTION

In March 1999, the American Chemistry Council (formerly the Chemical Manufacturers Association) Petroleum Additives Panel Health, Environmental, and Regulatory Task Group (HERTG), and its participating member companies committed to address data needs for certain chemicals listed under the Environmental Protection Agency (EPA) High Production Volume (HPV) Chemical Challenge Program. This test plan follows up on that commitment. Specifically, this test plan sets forth how the HERTG intends to address testing information for thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide, CAS Number: 18760-44-6.

In preparing this test plan the following steps were undertaken:

Step 1: A review of the literature and confidential company data was conducted on the physicochemcial properties, mammalian toxicity endpoints, and environmental fate and effects for thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide, using its CAS number, CAS name, and synonyms. Searches included the following sources: MEDLINE, BIOSIS, CANCERLIT, CAPLUS, CHEMLIST, EMBASE, HSDB, RTECS, EMIC, and TOXLINE databases; the TSCATS database for relevant unpublished studies on these chemicals; and standard handbooks and databases (e.g., Sax, CRC Handbook on Chemicals, IUCLID, Merck Index, and other references) for physicochemical properties.

Step 2: The compiled data was evaluated for adequacy in accordance with the EPA guidance documentation.

2.0 GENERAL SUBSTANCE INFORMATION

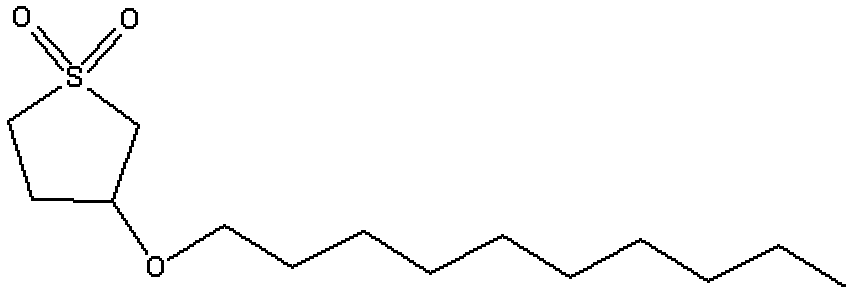
Chemical Name: thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide

Chemical Abstract Service Registry Number: CAS No.: 18760-44-6

Molecular Formula: $C_{14}H_{28}O_3S$

Molecular Weight: 276.4

Structural Diagram:



thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide
CAS No.: 18760-44-6

3.0 USE AND EXPOSURE INFORMATION

The substance 2- thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide is a lubricating additive in many types of internal combustion engine oils, automatic transmission fluids, and hydraulic fluids. This component is generally blended into finished oils and fluids where the typical concentration is less than 1 wt.% depending on the application.

The substance 2- thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide is manufactured and blended into additive packages at plants owned by one or more members of the HERTG. Finished lubricants are blended at facilities owned by our customers. Additive packages are shipped to customers in bulk in ships, isocontainers, railroad tank cars, tank trucks or in 55-gallon steel drums. The bulk additive packages are stored in bulk storage tanks at the customer blending sites. Finished oils are blended by pumping the lubricating oil blend stocks and the additive package from their storage tanks through computer controlled valves that meter the precise delivery of the components into a blending tank. After blending, the finished lubricant products are sold in bulk and shipped in tank trucks to large industrial users, such as manufacturing facilities and facilities that service truck fleets and passenger motor vehicles. Finished lubricants are also packaged into 55-gallon drums, 5-gallon pails, and one-gallon and one-quart containers for sale to smaller industrial users. Sales of lubricants in one-gallon and one-quart containers to consumers at service stations or retail specialty stores also occur.

Based on these uses, the potentially exposed populations include (1) workers involved in the manufacture of 2- thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide, blending this component into additive packages, and blending the additive packages into finished lubricants; (2) quality assurance workers who sample and analyze these products to ensure that they meet specifications; (3) workers involved in the transfer and transport of 2- thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide, additive packages or finished lubricants that contain this component; (4) mechanics who may come into contact with both fresh and used lubricants while working on engines or equipment; (5) gasoline station attendants and consumers who may periodically add lubricating oil to automotive crankcases; and (6) consumers who may change their own automotive engine oil. The most likely route of human exposure for these substances is through dermal contact. The most likely source of environmental exposure is accidental spills at manufacturing sites or during transport.

TABLE 1

SUMMARY TABLE OF AVAILABLE DATA

CAS No.: 18760-44-6	Study Date	Study Results	Data Acceptable
Physical/Chemical Characteristics			
Melting Point		Not Applicable	-
Boiling Point		No Data Located	-
Vapor Pressure		No Data Located	-
Partition Coefficient		No Data Located	-
Water Solubility	2002	54 mg/L at 20°C	Yes
Environmental Fate			
Photodegradation		No Data Located	-
Hydrolysis		No Data Located	-
Fugacity		No Data Located	-
Biodegradation	1997	9.6% at 28 days	Yes
Ecotoxicity			
Acute Toxicity to Algae	2002	EL_{50} (72 hrs) = 3.5 mg/L WAF NOEL = 0.313 mg/L WAF	Yes
Acute Toxicity to Invertebrates		No Data Located	-
Acute Toxicity to Fish		No Data Located	-
Mammalian Toxicity			
Acute Toxicity	1975 1975	Rat Oral LD_{50} >10 g/kg Rabbit Dermal LD_{50} between 4 and 8 g/kg	Yes Yes
Repeat Dose Toxicity		No Data Located	-
Developmental Toxicity		No Data Located	-
Reproductive Toxicity		No Data Located	-
Genetic Toxicity			
Gene Mutation	1980	Not Mutagenic	Yes
Chromosomal Aberration		No Data Located	-

TABLE 2

SUMMARY TABLE OF PROPOSED TESTING

Based on the data availability indicated in the above "Summary Table of Available Data" the following HPV Testing is proposed:

CAS No.: 18760-44-6	Testing Required	OECD Test Guideline or Testing Model Proposed
Physical/Chemical Characteristics		
Melting Point	Not Applicable	Not Applicabable
Boiling Point	Yes	103
Vapor Pressure	Yes	104
Partition Coefficient	Yes	117
Water Solubility	No	-
Environmental Fate		
Photodegradation	Yes	AOPWIN Model
Hydrolysis	No	Technical Discussion
Fugacity	Yes	Fugacity Level 1 Type Model
Biodegradation	No	-
Ecotoxicity		
Acute Toxicity to Algae	No	-
Acute Toxicity to Invertebrates	Yes	OECD 202
Acute Toxicity to Fish	Yes	OECD 203
Mammalian Toxicity		
Acute Toxicity	No	-
Repeat Dose Toxicity	Yes	OECD 422
Developmental Toxicity	Yes	OECD 422
Reproductive Toxicity	Yes	OECD 422
Genetic Toxicity		
Gene Mutation	No	-
Chromosomal Aberration	Yes	OECD 473

4.0 PHYSICAL CHEMICAL PROPERTIES

Physicochemical data (i.e., boiling point, vapor pressure, and log Ko/w) for 2- thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide were determined experimentally.

4.1 Boiling Point

The calculated boiling point for 2-thiophene, 3-(decyloxy)tetrahydro- 1,1-dioxide is 362.1^{o}C (Table 1). Experimental measurement is proposed using OECD Guideline 103.

4.2 Vapor Pressure

Modeling data indicate that the vapor pressure of 2-thiophene, 3-(decyloxy)tetrahydro-1,1-dioxide is approximately an 8e-006 mmHg @ 25 ^{o}C (Table 1). Experimental measurements are proposed using OECD Guideline 104.

4.3 Water Solubility

The water solubility of thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide determined according to EEC Commission Directive 92/69/EEC Method A6 is 54 mg/L at 20°C. Thus, the calculated and measured values are in close agreement.

4.4 Octanol-Water Partition Coefficient

The log octanol-water partition coefficient (log Ko/w) value of 2-thiophene, 3-(decyloxy)tetrahydro- 1,1-dioxide is calculated to be 3.6 (Table 1). Experimental measurements are proposed using OECD Guidelines 117.

5.0 ENVIRONMENTAL FATE DATA

5.1 Biodegradability

The Modified Strum Test (OECD Guideline 301B) was used to evaluate the biodegradability of thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide. After the 28-day test, the extent of biodegradation was 9.6% based on total carbon dioxide production. The available data are adequate and reliable. Additional biodegradation testing will not be conducted.

5.2 Hydrolysis

No published or unpublished hydrolysis studies on thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide were located. The potential for thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide to hydrolyze will be characterized in a technical discussion.

5.3 Photodegradation

No published or unpublished photodegradation studies of thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide were located. The Atmospheric Oxidation Potential (AOP) of this substance will be characterized using the modeling program AOPWIN.

5.4 Fugacity Modeling

No published or unpublished fugacity-based multimedia fate modeling data for thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide was located. The relative distribution among environmental compartments will be evaluated using Level I Fugacity modeling.

6.0 ECOTOXICOLOGY DATA

6.1 Aquatic Toxicity

The 96 hour EL_{50} of thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide determined in algae is 3.5 mg/L WAF. The NOEL is 0.313 mg/L WAF. The available aquatic toxicity data in algae are adequate and reliable. Additional aquatic toxicity testing in invertebrates and fish is proposed according to OECD Test Guidelines 202 and 203.

7.0 MAMMALIAN TOXICOLOGY DATA

7.1 Acute Mammalian Toxicity of Thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide

Acute oral and dermal toxicity studies are available for thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide. The LD_{50} in rats (oral) and rabbits (dermal) are >10 g/kg and between 4 and 8 g/kg, respectively. These studies were reviewed and considered reliable. Additional acute mammalian toxicity testing is not proposed.

7.2 Mutagenicity of Thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide

An adequate and reliable bacterial reverse mutation study was performed for thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide. Additional mutagenicity testing for chromosome aberrations will be performed according to OECD Test Guideline 473.

7.3 Repeated-dose, Reproductive and Developmental Toxicity of Thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide

No published or unpublished repeat dose, reproductive or developmental toxicity tests for thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide were located. Testing is proposed in the form of OECD Test Guideline 422: A Combined Repeated Dose Toxicity Study with a Reproduction/Developmental Toxicity Screening Test.

Substance Group: **Group 10**

Summary prepared by: **Petroleum Additives Panel**
Health & Environmental Research Task Group

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1.0 General Information

Robust Summary 10 -Water Solubility-1

<table>
<tr><td>CAS No.</td><td>18760-44-6</td></tr>
<tr><td>Test Substance Name</td><td>Thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide</td></tr>
<tr><td>Method/Guideline</td><td>EEC Commission Directive 92/69/EEC Method A6 Water solubility</td></tr>
<tr><td>GLP (Y/N)</td><td>Yes</td></tr>
<tr><td>Year</td><td>2002</td></tr>
<tr><td>Remarks for Test Conditions</td><td>To each of three conical flasks, distilled water and test substance were added. The flasks were stirred at 30°C, one each for 24, 48 and 72 hours, and after standing at 20°C the contents of the flasks were centrifuged at 10000 rpm for 30 minutes. The concentration of the test material in the sample solutions was determined by gas chromatography. Duplicate 200 ml aliquots of each sample were extracted with three 30 mL portions of dichloromethane. Extracts were filtered through anhydrous sodium sulphate. The combined extracts were then evaporated to dryness and the residue re-dissolved in 5 mL of tetrahydrofuran. Duplicate standard solutions of test material were prepared in tetrahydrofuran at a nominal concentration of 1.00×10^{3} mg/L</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th>Sample No.</th><th>Time Shaken at 30°C</th><th>Equilibration Time at 20°C</th><th>Concentration (g/l)</th><th>pH</th></tr>
<tr><td>1</td><td>24 hours</td><td>24 hours</td><td>5.50×10^{-2}</td><td>4.7</td></tr>
<tr><td>2</td><td>48 hours</td><td>24 hours</td><td>5.05×10^{-2}</td><td>5.3</td></tr>
<tr><td>3</td><td>72 hours</td><td>24 hours</td><td>5.66×10^{-2}</td><td>4.9</td></tr>
</table>
Mean concentration 5.4×10^{-2} g/l at 20°C $\pm$ 0.5°C

The analytical method was validated with respect to linearity and recovery of the test material from aqueous media. Instrument response was linear.</td></tr>
<tr><td>Conclusions</td><td>The water solubility of the test material was determined to be 5.4×10^{-2} g/l at 20°C $\pm$ 0.5°C</td></tr>
<tr><td>Data Quality</td><td>Reliable without restriction</td></tr>
<tr><td>References</td><td>Confidential business information</td></tr>
<tr><td>Other</td><td>November 21, 2002</td></tr>
</table>

2.0 Biodegradation

Robust Summary 10-BioDeg-1

Test Substance	
CAS #	18760-44-6
Chemical Name	Thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide
Remarks	Test material Purity– 100% active ingredient
Method	
Method/Guideline Followed	OECD 301B, Ready Biodegradability, Modified Sturm Test; ASTM Test Method D 5864-95.
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Y
Year (study performed)	1997
Contact time (units)	28 days
Test apparatus	Six glass 4-liter Erlenmeyer
Inoculum	Activated sewage sludge from a domestic wastewater treatment plant and soil filtrate prepared per test guideline. Six adaptation cultures were prepared. The inoculum was combined with 900 mL of test medium within a 2-liter flask. Solutions were continuously aerated with CO_2 free air and the test substance was incrementally added at concentrations of 4, 8 and 8 mg C/L on days 0, 7 and 11. (This adaptation of the inoculum to the test material is not called for in the OECD Guideline. This deviation from the Guideline was not considered sufficient to invalidate the study.) On day 14 a composite culture was prepared and homogenized. A standard plate count was performed. Plates were incubated at $20^{O}C$ for 48 hours.
Replicates:	*All groups tested in triplicate*
Temperature of incubation:	20+ 3°C
Dosing procedure:	Neat test chemical was gravimetrically added to glass cover slips, which were then added to culture medium in test vessels.
Study initiation:	Test flasks provided with 50-100 mL/minute CO_2 free air and mixed with a magnetic stirrer. The CO_2 produced from the degradation of organic carbon sources within each test chamber was trapped as K_2CO_3 in the KOH solution and measured using a carbon analyzer.
Sampling:	Days 4, 7, 12, 14, 19, 22 and 29 (after acidification on day 28)
Concentration of test substance:	10 mg carbon (C)/L weighed directly onto tared glass slides and placed into each test substance flask.
Controls:	Blank and positive controls used per guideline. Positive control was canola oil added to the control vessel at a loading of 10 mg C/L.
Analytical method:	The CO_2 produced from the degradation of organic carbon sources within each test chamber was trapped as K_2CO_3 in the KOH solution and measured using a carbon analyzer.
Study termination:	The pH of the content of each test flask was determined. The flasks were then acidified with 3 ml of concentrated hydrochloric acid to drive off inorganic carbonate. The chambers were aerated overnight and then the trapping solution closest to the test chamber was analyzed for inorganic carbon.
Method of calculating biodegradation values:	Percent biodegradation calculated as percent ratio of cumulative net carbon dioxide to theoretical carbon dioxide as determined from elemental analysis of test material.

Results	The test substance was not considered readily biodegradable under the criteria that requires 60% biodegradation within 28 days, achieved within 10 days of reaching 10% biodegradation. The CO_2 production from the reference chemical exceeded the 60% of theoretical necessary to consider the test valid.
Degradation % After Time	Test substance: 9.6 $\pm$ 3.0% TCO_2 in 28days Positive control substance: 76.9 $\pm$ 9.5% % in 28 days Final pH: 6.37
Conclusions	The test substance was not readily biodegradable.
Data Quality	(1) Reliable without restriction
References	This robust summary was prepared from an unpublished study by an individual member company of the HERTG (the underlying study contains confidential business information).
Other	Updated: 11/21/2002

3. Ecotoxicity

AQUATIC ORGANISMS

3.1 Acute Toxicity to Algae

Robust Summary 10-Algae-1

Test Substance	
CAS #	18760-44-6
Chemical Name	Thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide
Remarks	Test material purity – 100% active ingredient
Method	
Method/Guideline followed	OECD Guideline for Testing of Chemicals #201 Alga, Growth Inhibition Test (1984).
Test Type	Static acute toxicity test (Water Accommodated Fraction- WAF)
GLP (Y/N)	Y
Year (Study Performed)	2002
Species/Strain	Freshwater algae, *Scenedesmus subspicatus*/CCAP 276/20
Element basis (# of cells/mL)	Approximately 2.45 x 10^6 cells/mL, 5 mL used to inoculate 1 liter of medium for an initial cell density of 10^4 cells/mL.
Exposure period/duration	72 hours
Range find test	Yes
Analytical monitoring	Not performed
Statistical methods	One-way analysis of variance, Bartlett's test and Dunnett's test were used to compare the area under the growth curve data of the treated and control groups.
Remarks field for test conditions (fill as applicable)	Test Species: Cultures obtained from the Culture Collection of Algae and Protozoa (CCAP), Institute of Freshwater Ecology, The Ferry House, Far Sawrey, Ambleside, Cumbria, U.K. Loading Concentrations: 0.313, 0.625, 1.25, 2.5, 5.0 and 10 mg/L loading rate WAF. Test System: The WAF was prepared only at the beginning of the test. A measured weight of test material was added to a measured volume of culture medium (10-L) in a glass vessel and stirred for 24 hours. Stirring accomplished using a magnetic stirrer. Mixing speed was adjusted such that a slight vortex formed. Following the mixing period, the test solutions were allowed to stand for one hour. A small amount of each WAF was removed and examined microscopically for the presence of micro-dispersions or globules of test material. None were observed therefore the WAF was removed from each concentration by mid-depth siphoning. The siphoned water phase (i.e., WAF) was used for the aquatic toxicity test. Test Conditions: A static test was conducted; i.e., there was no daily renewal of test solution. Three 100-mL replicates per treatment, inoculum ~10,000 cells/mL. The 250-mL conical flasks were plugged with polyurethane foam bungs. During the test all treatment and control flasks were randomly placed on an orbital shaker adjusted to approximately 150 cycles per minute under constant light (24 hours/day) for 72 hours. Cell densities were determined using a Coulter Multisizer II Particle Counter at 0, 24, 48 and 72 hours. pH was determined at 0 and 72 hours.

	Light: Continuous illumination approximately 7000 lux. Test temperature: 21.0^{o} C. Culture Media: As specified in the guideline. Method of calculating mean measured concentrations: not applicable Exposure period: 72 hours
Results	EL50(72 hrs)= 3.5 mg/L loading rate WAF [Loading rate that reduced the biomass by 50%]. EL50(0-72 hrs)= 63 mg/L loading rate WAF [Loading rate that reduced specific growth rate by 50%, determined by extrapolation as no concentration resulted in greater than 50% growth inhibition]. There were no statistically significant differences in the area under the growth curve data between the control and 0.313 mg/L WAF test group, however all other loading rates were significantly reduced compared to control. Therefore the No Observed Effect Loading Rate (NOEL) was 0.313 mg/L WAF. The cell concentrations of the control cultures increased by a factor of 69 during the study meeting the guideline requirement of at least a factor of 16 after 72 hours. All test and control cultures were inspected microscopically at 72 hours. No abnormalities were observed in any cultures. Control culture pH increased from 7.4 at 0 hour to 7.9 at 72 hours. This is consistent with the guideline. In the test cultures pH increased over the 72 hour test period following a concentration dependent pattern. Greater increases were observed at lower concentrations. This was attributed to a greater number of viable cells at lower concentrations with greater utilization of carbonates and bicarbonates from respiration.
Conclusions	Both biomass and growth rate were affected by the presence of the test material. EL50 (72 hrs)= 3.5 mg/L loading rate WAF EL50 (0-72 hrs)= 63 mg/L loading rate WAF No Observed Effect Loading Rate (NOEL) = 0.313 mg/L loading rate WAF Control response was satisfactory.
Data Quality	(1) Reliable without restriction
References	Confidential business information.
Other	Updated: 11/19/2002

4. Toxicity Category:

4.1 Acute Toxicity

4.1.1 Acute Oral Toxicity

Robust Summary 10-Acute Oral-1

Test Substance	
CAS #	CAS# 18760-44-6
Chemical Name	Thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide
Remarks	Test material dosed as received, purity - 100% active ingredient.
Method	
Method/Guideline followed	FHSA 16CFR1500.3
Test Type	Acute oral toxicity
GLP (Y/N)	N
Year (Study Performed)	1975
Species/Strain	Rats/Wistar
Sex	Male/female
No. of animals/sex/dose	5
Vehicle	None
Route of administration	Oral (intragastric)
Dose level	0.67, 1.25, 2.5, 5.0 and 10 ml/kg
Dose volume	Not specified
Control group included	No
Remarks field for test conditions	A single dose of the undiluted test material was administered intragastrically to five fasted male and female rats at each treatment level. A control group was not included. The animals were observed for signs of toxicity and mortality for a total of fourteen days. Individual weights were recorded at termination. All animals were euthanized at the conclusion of the observation period. Necropsies were not performed.
Results	Oral LD50 > 10 g/kg (males and females)
Remarks	All animals survived the duration of the study. There were no signs of toxicity observed in any of the animals. The LD50 was > 10 g/kg (males and females).
Conclusions	The test article, when administered as received to male and female Wistar rats, had an acute oral LD50 > 10 g/kg (males and females).
Data Quality	Reliable with restriction (Klimisch Code). Restriction due to the fact that this is a summary report. The report contains group summary data but not individual animal data. This is consistent with standard practice at the time that this study was conducted.
References	Unpublished confidential business information
Other	Updated: 11/15/2002

4.1.2 Acute Dermal Toxicity

Robust Summary 10-Acute Dermal-1

Test Substance	
CAS #	CAS# 18760-44-6
Chemical Name	Thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide
Remarks	Test material purity - 100% active ingredient.
Method	
Method/Guideline followed	Similar to OECD Guideline 402
Test Type	Acute dermal toxicity
GLP (Y/N)	Not specified
Year (Study Performed)	1975
Species/Strain	Rabbits/strain not specified
Sex	Male
No. of animals/group	3
Vehicle	None
Route of administration	Dermal
Dose level	2, 4 and 8 g/kg
Dose volume	Not provided
Control group included	No
Remarks field for test conditions	The test material was applied using a syringe under a rubber sleeve that was snugly fastened around the unabraded clipped trunk of the test animal. The animals were immobilized for a 24-hour period immediately following treatment. At the end of the 24-hour period the sleeves were removed and the animals were returned to their cages for a 14-day observation period during which the animals were observed for evidence of toxicity and mortality.
Results	Dermal LD50 was between 4 and 8 g/kg (males)
Remarks	All animals treated at 2 and 4 g/kg survived the duration of the study. The three animals treated at 8 g/kg died on test days 5, 5 and 7. All animals treated at 2 and 4 g/kg exhibited slight weight gain during the study. No significant signs of toxicity were reported.
Conclusions	The test article, when administered dermally as received to male white rabbits had an acute dermal LD50 of between 4 and 8 g/kg.
Data Quality	Reliable with restriction (Klimisch Code). Restriction due to the failure to include individual animal clinical data in the report. This is consistent with standard practice at the time that this study was conducted.
References	Unpublished confidential business information
Other	Updated: 11/15/2002

4.2 Genetic Toxicity

Robust Summary 10-GenTox-1

Test Substance	
CAS #	CAS# 18760-44-6
Chemical Name	Thiophene, 3-(decyloxy)tetrahydro-, 1,1-dioxide
Remarks	Test material purity – 100% active ingredient.
Method	
Method/Guideline followed	Similar to OECD Guideline 471
Test Type	Bacterial Reverse Mutation Assay
GLP (Y/N)	Y
Year (Study Performed)	1980
Test System	*Salmonella typhimurium* and *Escherichia Coli*
Strains Tested	*Salmonella typhimurium* tester strains TA98, TA100, TA1535, TA1537; TA1538 *Escherichia Coli* tester strain WP2*uvr*A
Exposure Method	Plate incorporation
Test Substance Doses/concentration levels	1, 5, 10, 50, 100, 500, 1000 and 5000 ug/plate
Metabolic Activation	With and without (0.5 mL S9 fraction mix of livers of PCB pretreated Sprague Dawley rats)
Vehicle	Dimethylsulfoxide
Tester strain, activation status, Positive Controls and concentration level	TA98 +S9 2-aminoanthracene 0.5 ug/plate TA98 -S9 2-aminofluorene 0.1ug/plate TA100 +S9 2-aminoanthracene 0.5 ug/plate TA100 -S9 2-aminofluorene 0.01ug/plate TA1535 +S9 2-aminoanthracene 2.0 ug/plate TA1535 -S9 N-ethyl-N-nitro-N-nitrosoguanidine 5.0 ug/plate TA1537 +S9 2-aminoanthracene 2.0 ug/plate TA1537 -S9 9-aminoacridine 80.0 ug/plate TA1538 +S9 2-aminoanthracene 0.5 ug/plate TA1538 -S9 2-nitrofluorene 2.0 ug/plate WP2uvrA +S9 2-aminoanthracene 80.0 ug/plate WP2uvrA –S9 2-aminofluorene 0.04 ug/plate
Vehicle Control	Dimethylsulfoxide
Statistical Analysis	Mean revertant colony count was determined for each dose point.
Dose Rangefinding Study	None reported
S9 Optimization Study	None reported
Remarks field for test conditions	This study was conducted prior to the development of OECD Test Guideline 471. The study included the use of tester strain TA1538. OECD 471 does not incorporate this strain. This deviation from the test guideline was not considered a major study deficiency. There were two treatment sets for each tester strain, with (+S9) and without (-S9) metabolic activation. Each of the tester strains was dosed with eight concentrations of test substance, vehicle controls, and a positive control. Two plates/dose group/strain/treatment set were evaluated. 0.1 mL of test material, positive control or vehicle control were added to each plate along with 0.1 ml of tester strain, 0.5 mL of S9 mix (if needed) and 2.0 ml of top agar. This was overlaid onto the surface of minimal bottom agar in a petri dish. A sterility culture was

	also prepared. Plates were incubated for 48 hours at 37°C. The revertant colonies on the test plates and the control plates were then counted. The test substance was considered positive if the number of revertant colonies (mean value) was more than twice that of the solvent control and exhibited a dose response.
Results	The test substance was not genotoxic in this assay with or without metabolic activation.
Remarks	The test substance failed to exhibit a positive response with or without metabolic activation at any concentration tested. The positive control for each respective test strain exhibited at least a 2-fold increase (with or without S9) over the mean value of the vehicle control for a given strain, confirming the expected positive control response.
Conclusions	Under the conditions of this study, the test material was not mutagenic with or without metabolic activation.
Data Quality	Reliable without restriction (Klimisch Code)
References	Unpublished confidential business information
Other	Updated: 11/19/2002